

Amendment to the Claims:

The following listing of claims is intended to replace all previous claims.

Listing of Claims:

1-106. (canceled).

107. (previously presented) A method for determining the optimal conditions for sterilizing a tissue containing collagen without adversely affecting a predetermined biological characteristic or property of the tissue, comprising

- (i) irradiating the collagen under a pre-determined set of conditions effective to sterilize the tissue;
- (ii) determining the turbidity of the irradiated collagen; and
- (iii) repeating steps (i) and (ii) with a different pre-determined set of conditions until the turbidity of the irradiated collagen reaches a pre-determined acceptable level.

108-124. (canceled)

125. (currently amended) A method for reducing the level of active biological contaminants or pathogens in one or more tissues, comprising

contacting the one or more tissues with a composition comprising propylene glycol, at least one other polyhydric alcohol, and a penetration enhancer effective to increase penetration of the composition into the one or more tissues, and

irradiating the one or more tissues with gamma radiation,
wherein the total dose of gamma radiation is at least about ~~35~~ 25 kGy.

126. (currently amended) The method of claim ~~124 or~~ 125 wherein the one or more tissues is hard tissue.

127. (previously presented) The method of claim 126 wherein the hard tissue is selected from the group consisting of bone, demineralized bone matrix, joints, femurs, femoral heads and teeth.

128. (currently amended) The method of claim ~~124 or~~ 125 wherein the one or more tissues is soft tissue.

129. (previously presented) The method of claim 128 wherein the soft tissue is selected from the group consisting of collagen, connective tissue, epithelial tissue, adipose tissue, bone marrow, ligaments, tendons, nerves, nerve cells, skin grafts, heart valves, portions of brain, cartilage, corneas, arteries and veins.

130. (currently amended) The method of claim ~~124 or~~ 125 wherein the one or more tissues is a combination of hard and soft tissue.

131. (currently amended) The method of Claim ~~124 or~~ 125 wherein the one or more tissues is at a temperature below its freezing point during irradiation.

132. (previously presented) The method of claim 131 wherein the one or more tissues is at a temperature of about 0° C to about -196° C during irradiation.

133. (previously presented) The method of claim 131 wherein the one or more tissues is at a temperature of about -50° C to about -78° C during irradiation.

134. (currently amended) The method of claim ~~124 or~~ 125 wherein the one or more tissues is maintained in an inert atmosphere during irradiation.

135. (currently amended) The method of Claim ~~124 or~~ 125 wherein the one or more tissues is maintained under vacuum during irradiation.

136. (currently amended) The method according to claim ~~124~~ or 125 wherein the irradiation is applied at a rate of at least about 0.3 kGy/hour to at least about 30.0 kGy/hour.

137. (currently amended) The method of claim ~~124~~ 125 wherein the total dose of gamma irradiation is at least about 30 kGy.

138. (currently amended) The method of claim ~~124~~ or 125 wherein the total dose of gamma irradiation is at least about 45 kGy.

139. (currently amended) The method of claim ~~124~~ or 125 wherein the total dose of gamma irradiation is at least about 50 kGy.

140. (currently amended) The method of claim ~~124~~ or 125 wherein the concentration of the propylene glycol is at least about 20 mM to about 1 M.

141. (currently amended) The method of claim ~~124~~ or 125 wherein the concentration of the propylene glycol is at least about 100 mM to about 500 mM.

142. (currently amended) The method of claim ~~124~~ 125 wherein the at least one other polyhydric alcohol ~~other stabilizers are~~ is selected from the group consisting of DMSO, mannitol, and trehalose, glycerol, inositol and sorbitol.

143-148. (canceled)

149. (currently amended) The method of claim ~~124~~ or 125 further comprising adjusting or maintaining the pH of the one or more tissues prior to irradiation.

150. (currently amended) The method of claim ~~124~~ or 125 further comprising reducing residual solvent content of the one or more tissues prior to irradiation.

151. (previously presented) The method of claim 150 wherein the residual solvent is a non-aqueous solvent.

152. (previously presented) The method of claim 150 wherein the residual solvent is an aqueous solvent.

153. (previously presented) The method of claim 150 wherein the residual solvent content is reduced by a method selected from the group consisting of lyophilization, drying, addition of a second solvent, evaporation, chemical extraction and vitrification.

154. (currently amended) The method of claim 150 wherein the residual solvent content is reduced to about ~~about~~ six to about eight percent.

155. (canceled)

156. (canceled)

157. (currently amended) The method of claim ~~124 or~~ 125 further comprising contacting the one or more tissues with at least one sensitizer prior to irradiation.

158. (previously amended) The method of claim 157 wherein the at least one sensitizer is selected from the group consisting of psoralen; 3-carboethoxy psoralen; inactines; angelicins; khellins; coumarins; brominated hematoporphyrin; phthalocyanines; purpurins; porphyrins; halogenated or metal atom-substituted derivatives of dihematoporphyrin esters; hematoporphyrin derivatives; benzoporphyrin derivatives; hydrodibenzoporphyrin dimaleimide; hydrodibenzoporphyrin; dicyano disulfone; tetracarbethoxy hydrodibenzoporphyrin; tetracarbethoxy hydrodibenzoporphyrin dipropionamide; doxorubicin; daunomycin; netropsin; BD peptide; S2 peptide; S-303 (ALE compound); hypericin; methylene blue; eosin; fluoresceins; flavins; merocyanine 540; bergapten; SE peptide; Cu^{2+} and Cu^{3+} and combinations thereof.

159. (currently amended) The method of claim ~~124 or~~ 125 wherein the one or more tissues contains at least one biological contaminant or pathogen selected from the group

consisting of viruses, bacteria, yeasts, molds, fungi, parasites, prions, causative agents of transmissible spongiform encephalopathies and combinations thereof.

160 – 164. (canceled)

165. (currently amended) The method of claim ~~124~~ or 125 wherein the one or more tissues are packaged prior to said irradiation.

166. (currently amended) A composition comprising one or more tissues prepared according to the method of claim ~~124~~ 125.

167. (canceled)

168. (canceled).

169. (canceled)

170. (new) The composition of claim 166 wherein the one or more tissues comprises propylene glycol; at least one other polyhydric alcohol selected from the group consisting of mannitol, trehalose, glycerol, inositol, and sorbitol; and a penetration enhancer.

171. (new) The composition of claim 170, wherein the composition comprises DMSO.

172. (new) The method of claim 142, wherein the composition comprises DMSO.